

REMARKS**Status of the Claims**

Claims 1-15 and 23-32 are currently pending. Claim 16-22 has been cancelled without prejudice or disclaimer of the subject matter claimed therein. New claims 23-32, directed to the same invention as claims 1-15, have been added. Claims 1-15 and 23-32 are currently under examination.

Support for the Amendments to the Claims

Claims 1, 3, 6, and 10-14 have been amended and claims 23-32 have been added. Support for the amendments to the claims can be found throughout the specification. Representative support is summarized below.

Representative support for the amendment to claim 1 can be found in claim 1 as originally filed and on page 6, lines 24-26.

Claims 3, 6, and 10-13 have been amended to delete specific embodiments that are recited in new claims 23-32.

Claim 14 has been amended to delete “e.g.” from the claim.

New claims 23-32 have been added. Representative support for new claims 23-25 can be found in claim 3 as originally filed. Representative support for new claims 26-28 can be found in claim 6 as originally filed. Representative support for new claim 29 can be found in claim 10 as originally filed. Representative support for new claim 30 can be found in claim 11 as originally filed. Representative support for new claim 31 can be found in claim 12 as originally filed. Representative support for new claim 32 can be found in claim 13 as originally filed.

The amendments to the claims do not add prohibited new matter.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-15 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The Office Action alleges that the phrase “performed without any further steps” is indefinite. Without acquiescing to the propriety of the rejection, claim 1 has been amended to clarify that step (c) is a self assembly process.

The Office Action also alleges that the recitation of several numerical ranges in claims 3 and 6 renders the claims indefinite for not clearly defining the metes and bounds. Claims 3 and 6 have been amended to delete numerical ranges that are recited in dependent claims 23-25.

The Office Action also alleges that the recitation of the terms “particularly” and “preferably” in claims 10-13 render the claims indefinite. These claims have been amended to delete embodiments that are recited in dependent claims 26-32.

Accordingly, Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 8-11, and 15 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Huang (Huang).

The Office Action alleges that Huang discloses the loading of cationic micelles with active agents such as nucleic acids, drugs, and proteins. However, Huang does not disclose the claimed invention because the reference does not disclose active agents that penetrate the membrane. In the Examples, Huang only discloses preparing DNA/lipid complexes, but DNA does not penetrate the membrane. Accordingly, Huang does not disclose every element of the claims, as amended. Therefore, Applicants respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 1-15 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Slater *et al.* (Slater), supported by Cullis *et al.* (Cullis).

Slater discloses compositions and methods of preparing liposome comprising topoisomerase inhibitors by “remote loading” (*see Slater et al.* at Col. 21, lines 1-20). The “remote loading” process used by Slater to produce loaded liposomes involves generating an ion gradient over the liposomal membranes to provide a driving force for the loading process (col. 10, lines 38-49). In contrast to the “self-assembly” process, the “remote loading” process is not a spontaneous process and requires external force such as mechanical forces (*e.g.* vigorous stirring or extrusion) or external activation energy, to drive the process. Thus, Slater does not disclose the claimed invention.

The Office Action relies on Cullis for teaching the use of pH changes to affect liposomes. However, Cullis does not teach spontaneous self-assembly process. Cullis only discloses

processes that occur in response to a pH gradient. Moreover, Cullis' description of "high activation energies for transmembrane transport of the neutral form of the drug" on page 195 (right column) of the reference confirms that the processes are not spontaneous, self-assembly processes.

Further, the Office Action relies on Figure 5 of Cullis to show that temperature is directly related to the uptake of drug by liposome. Thus, Cullis teaches that heating is needed to achieve reasonable loading efficiency. Accordingly, Cullis does not disclose a self-assembly process for preparing liposomal composition and does not cure the deficiencies of Slater.

Therefore, there is no reason to combine the teachings of the cited references and to modify the teachings of Slater to arrive at the claimed invention with reasonable expectation of success. It is therefore respectfully requested that this rejection be withdrawn.

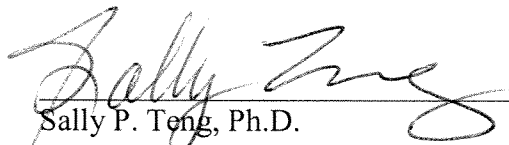
Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,
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